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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,969	01/05/2001	Lee Min Lau	15129.11	5154

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EXAMINER

BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/755,969

Applicant(s)

LAU ET AL.

Examiner

Carolyn M Bleck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5 January 2001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 5 January 2001.

Claims 1-31 are pending. The IDS statement filed 5 January 2001.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner respectfully submits that it is unclear what a "health data dictionary" is. Is it a computer database? Is it a book? Applicant is respectfully requested to clarify the current language within claims 1, 13, and 23, and several of the dependent claims.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-11, 13-21, and 23-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

(A) For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example), and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the process must somehow apply, involve, use, or advance the technological arts.

In the present case, claim 1 only recites an abstract idea. The recited steps of merely receiving the clinical data from the legacy system at a health data dictionary, translating the clinical data by the health data dictionary such that the clinical data has a new format that is compatible with the standard, comparing the new format of the clinical data with the standard of the clinical data, and when a match is found between the new format of the clinical data and the standard of the clinical data, an act of identifying one or more concept identifiers for the clinical data does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper. These steps only constitute an idea of how to classify a prospective insured into an appropriate risk group.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention identifies concept identifiers (i.e., repeatable) used to translate and store legacy data (i.e., useful and tangible).

Although the recited process produces a useful, concrete, and tangible result, since the claimed invention as a whole, is not within the technological arts as explained above, claim 35 is deemed to be directed to non-statutory subject matter.

(B) Similar analysis can be applied to independent claims 13 and 23. Therefore those claims are rejected for the same reasons as claim 1.

(C) Claims 2-11, 14-21, and 24-30 inherit the above deficiencies through dependency, and are thus rejected for the same reasons provided for claims 1, 13, and 23, and incorporated herein.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCallum (5,784,635) in view of Forrey (Forrey, Arden, et al., Logical observation

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identifier names and codes (LOINC) database; a public use set of codes and names for electronic reporting of clinical laboratory test results, *Clinical Chemistry*, 42:1 81-90 (1990)).

(A) As per claims 1 and 11, McCallum discloses a method for rationalizing physician data in which source data is collected from source computers at testing laboratories, wherein the source data is expected to be diverse formats and syntax, wherein source data is converted to a common format (Abstract), comprising:

(a) extracting and transferring source data to a processor, wherein the source data may be collected in any format, wherein the data is exported from various hardware/ software/ operating system configurations as used in computer systems in testing laboratories (col. 3 lines 5-11, col. 4 lines 57-67);

(b) standardizing the data by a conversion module such that the laboratory testing data is converted to a uniform format (Fig. 1-3, col. 4 line 57 to col. 5 line 45, col. 11 lines 10-68); and

(c) comparing the data that is in a standardized or uniform format with the standardized information of resources (Fig. 1-3, col. 4 line 57 to col. 5 line 45 (see col. 5 lines 39-44), col. 11 lines 10-68).

McCallum fails to expressly disclose "identifying one or more concept identifiers for the clinical data."

Forrey discloses identifying one of LOINC names related to the LOINC code (Table 7, pg. 86, col. 1 par. 4-5).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Forrey within the method of McCallum with the motivation of allowing receiving systems to understand the results they receive by providing a standardized format (Forrey; pg. 81, col. 2), and merging results from different sources to allow physician's to review the data (Forrey; pg. 81, col. 2, McCallum; col. 1 lines 15-49).

(B) As per claim 2, McCallum discloses a conversion engine and application program to perform the conversion (col. 6 lines 46-67, col. 13 line 22 to col. 14 line 25).

(C) As per claim 3, McCallum discloses accessing databases using the application program (col. 4 line 40 to col. 5 line 45, col. 6 line 47 to col. 7 line 5, col. 11 lines 10-67).

(D) As per claim 4, Forrey discloses identifying attributes of the data (pg. 82, col. 1 par. 2). The motivation for combining Forrey within McCallum is given above in claim 1, and incorporated herein.

(E) As per claim 5, McCallum discloses parsing the laboratory data (col. 6 line 46 to col. 7 line 5).

(F) As per claim 6, Forrey discloses the attributes corresponding to LOINC (pg. 82, col. 1 par. 2).

(G) As per claim 8, McCallum discloses source data being cleaning against tables (Abstract, col. 5 lines 25-39).

(H) As per claim 9, McCallum discloses adding the cleaned data to a single-format database of uniform data structure (col. 11 lines 10-52). McCallum fails to expressly disclose one or more concept identifiers being stored with the clinical data. Forrey discloses storing the LOINC names in a database (Table 7; pg. 82 col. 1 par. 1-2). At the time the invention was made, it would have been obvious to combine the teachings of Forrey within the method of McCallum with the motivation of allowing laboratories to use their existing files (pg. 82 col. 1 par. 1-2), thus reducing the amount of time to transfer different types of files from existing systems.

(I) As per claim 10, McCallum discloses extracting laboratory data from computer based information systems (col. 4 line 51 to col. 5 line 43).

(J) As per claim 12, McCallum discloses a processor with memory having conversion software for performing the method of claim 1 (col. 10 lines 9-27).

8. Claims 1-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCallum (5,784,635) and Forrey (Forrey, Arden, et al., Logical observation identifier names and codes (LOINC) database; a public use set of codes and names for

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electronic reporting of clinical laboratory test results, Clinical Chemistry, 42:1 81-90 (1990)) in view of claim 1, and further in view of Davis et al. (6,757,692).

(A) As per claim 7, McCallum and Forrey fail to expressly disclose synonym tables.

Davis discloses inputting data which is compared against a synonym list, wherein the data is compared based on matching algorithms which make use of the lexical characteristics to determine synonymous words and multiple concepts (col. 1 lines 26-45, col. 6 lines 35-56). At the time the invention was made, it would have been obvious to one of ordinary skill in the art to combine the features of Davis within the teachings of McCallum Forrey with the motivation of determining multiple matching concepts dealing with a particular term in science or technology (Davis; col. 1 lines 26-45).

9. Claims 13-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baorto (Baorto, David, et al., Using logical observation identifier names and codes (LOINC) to exchange laboratory data among three academic hospitals, Fall 1997, Proceedings AMIA Annual Fall Symposium (see Google scholar for cite)) in view of Davis et al. (6,757,692).

(A) As per claims 13, 16-17, 20-21, and 23-30, Baorto discloses a method comprising:

(a) extracting raw data from a local laboratory information system to a system dictionary, where each local test name is mapped to a LOINC identifier (pg. 1, col. 2 par. 2-3);

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(b) creating mappings between the local test name and LOINC names using coding rules (pg. 2; col. 2, par. 2);

(c) receiving the laboratory results at the system dictionary (pg. 1, col. 2 par. 2-3, pg. 2 col. 2 par. 3).

Baorto fails to expressly disclose creating synonym tables for the attributes of the unique laboratory results, deriving attributes from the laboratory results using the synonym table, generating a legacy relationship set for the laboratory results from the derived attributes, and comparing the legacy relationship set with the standard relationship sets. Davis discloses these features: data is input into working tables where terms contained in the input data are compared against previously input terms and against one or more synonym lists, wherein terms that are identifiable with known or similar term related a specific area of medicine are defined as a verbatim term, wherein duplicate verbatim terms that are identified are eliminated, wherein the verbatim terms are compared against known or desired terms and concepts related to the area of medicine and are then classified by associating each term with a specific area of medicine (col. 6 line 15 to col. 7 line 44).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to combine the teachings of Davis within the method of Baorto with the motivation of allowing receiving systems to understand the results they receive by providing a standardized format, and merging results from different sources to allow physician's to review the data.

(B) As per claim 14, Baorto discloses identifying attributes of the data (pg. 82, col. 1 par. 2).

(C) As per claim 15, Baorto discloses determining whether there is a match between the result and match and deciding whether to add the term (pg. 2, col. 2, par. 4 to pg. 4 col. 2 par. 3).

(D) As per claim 19, Baorto discloses attribute properties including component attribute, property attribute, time attribute, system attribute, scale attribute, and method attribute (pg. 3 col. 2 par. 3).

(E) As per claims 22 and 31, Baorto discloses using a commercial software package on a computer (pg. 2, col. 1 par. 3).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches multi-user system for creating and maintaining a medical-decision-making knowledge base (6,353,817), method and apparatus for knowledgebase searching (6,178,416), method for extracting pre-defined data items from medical service records generated by healthcare providers (5,664,109), automatic transmission of legacy system data (5,857,194), system and method for indexing information about entities from different information sources

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(5,991,758), system for assembling large databases through information extracted from text sources (6,052,693), system for retrieval of information from data structure of medical records (6,438,533), displaying implicit associations among items in loosely-structured data sets (6,629,097), method for organizing and using a statement library for generating clinical reports and retrospective queries (US 2002/0082825), method of processing test information (US 2004/0210586), and method and system for reporting XML data from a legacy computer system (6,687,873). The following non-patent literature is also pertinent to Applicant's disclosure: Development of the LOINC vocabulary (Huff), reinventing public health (Lee), design of platform independent ICU charting environment using HL7 and LOINC messaging (Delaney), standard for health claims attachments one potential HIPAA benefit (IT Health Care Strategist), LISs: Functionality (Golightly), A concept-based medication vocabulary: an essential requirement for pharmacy decision support (Broverman), and electronic laboratory-based reporting for public health (Pinner).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. After April 13, 2005, the Examiner can be contacted at (571) 272-6767. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9306 or (703) 872-9326 [Official communications]

(703) 872-9327 [After Final communications labeled "Box AF"]

(703) 746-8374 [Informal/ Draft communications, labeled
"PROPOSED" or "DRAFT"]

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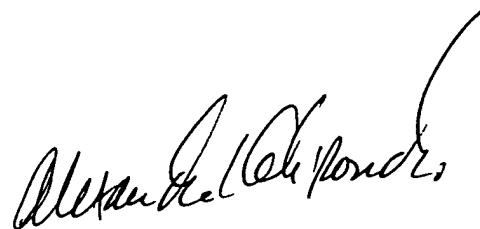
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Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive,
Arlington, VA, 7th Floor (Receptionist).

CB

CB

February 17, 2005

A handwritten signature in black ink, appearing to read "Alexander Kalinowski", with a long, sweeping flourish extending from the end.

ALEXANDER KALINOWSKI
PRIMARY EXAMINER